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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/511,345	10/15/2004	Kazuaki Hirasawa	38331-0005	3763	
	7590 01/04/200 MAN WHITE & MCA	•	EXAMINER		
1717 RHODE I	SLAND AVE, NW		MARX, IRENE  ART UNIT PAPER NUMBER		
WASHINGTO	N, DC 20036-3001				
			1651		
SHORTENED STATUTOR	Y PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
3 MO	NTHS	01/04/2007	PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

		Application No.	Applicant(s)			
		10/511,345	HIRASAWA ET AL.			
Office Action Summary		Examiner	Art Unit			
		Irene Marx	1651			
Period fo	The MAILING DATE of this communication ap or Reply	pears on the cover shee	t with the correspondence address			
WHIC - Exter after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR REPL CHEVER IS LONGER, FROM THE MAILING D nsions of time may be available under the provisions of 37 CFR 1. SIX (6) MONTHS from the mailing date of this communication. O period for reply is specified above, the maximum statutory period are to reply within the set or extended period for reply will, by statutively received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	PATE OF THIS COMMU 136(a). In no event, however, ma will apply and will expire SIX (6) is e. cause the application to become	INICATION. y a reply be timely filed  MONTHS from the mailing date of this communication e ABANDONED (35 U.S.C. § 133).			
Status						
1)	Responsive to communication(s) filed on					
•	•	s action is non-final.				
3)	Since this application is in condition for allowa	ince except for formal n	natters, prosecution as to the merits is	s		
	closed in accordance with the practice under	Ex parte Quayle, 1935	C.D. 11, 453 O.G. 213.			
Dispositi	ion of Claims					
4)🛛	Claim(s) <u>1-6</u> is/are pending in the application.					
	4a) Of the above claim(s) is/are withdrawn from consideration.					
5)[	Claim(s) is/are allowed.					
6)⊠	Claim(s) <u>1-6</u> is/are rejected.					
7)	Claim(s) is/are objected to.					
8)□	Claim(s) are subject to restriction and/o	or election requirement.				
Applicati	ion Papers	•				
9)	The specification is objected to by the Examine	er.				
10)	The drawing(s) filed on is/are: a) acc	cepted or b)  objected	to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
	Replacement drawing sheet(s) including the correct	tion is required if the draw	ing(s) is objected to. See 37 CFR 1.121(	d).		
11)	The oath or declaration is objected to by the E	xaminer. Note the attac	hed Office Action or form PTO-152.			
Priority ι	under 35 U.S.C. § 119	·		•		
a)[	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority document application from the International Burea See the attached detailed Office action for a list	ts have been received. ts have been received i ority documents have be u (PCT Rule 17.2(a)).	n Application No een received in this National Stage			
2) Notic	t(s)  e of References Cited (PTO-892)  e of Draftsperson's Patent Drawing Review (PTO-948)  mation Disclosure Statement(s) (PTO/SB/08)	Paper	ew Summary (PTO-413) No(s)/Mail Date of Informal Patent Application			
Pape	·					

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## **DETAILED ACTION**

The application should be reviewed for errors.

To facilitate processing of papers at the U.S. Patent and Trademark Office, it is recommended that the Application Serial Number be inserted on every page of claims and/or of amendments filed.

Claims 1-6 are pending and subject to restriction.

## Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "wherein the DNA sequence that **corresponds** to the microorganism's 16S ribosomal RNA is **substantially homologous** to the sequence as shown in SEQ ID NO:1". The degree of correspondence between DNA and RNA is unclear. In addition, the scope of "substantially homologous" cannot be readily determined.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-3 and 5-6 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The invention appears to employ a specific mutant strains to obtain certain amounts of canthaxanthin. It is not clear if the written description is sufficiently repeatable to avoid the need for a deposit. Further it is unclear if the starting materials were readily available to the public at the time of invention.

It does not appears that a deposit was made in this application that meets all of the criteria set forth in 37 CFR 1.801-1.809. Applicant or applicant's representative may provide assurance of compliance with the requirements of 35 U.S.C § 112, first paragraph, in the following manner. SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

- 1. Identifies declarant.
- 2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.
- 3. States that the deposited material has been accorded a specific (recited) accession number.
- 4. States that all restriction on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.
- 5. States that the material has been deposited under conditions that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C § 122.
- 6. States that the deposited material will be maintained with all the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty (30) years after the date of deposit for the enforceable life of the patent, whichever period is longer.
- 7. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

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Alternatively, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Tsubokura *et al*.

The claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin..

Tsubokura *et al.* teach to a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, e.g., Example 3.

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Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsubokura et al.

The claims are directed to a process of mutating and culturing a strain such as a mutant of strain E-396 for the production of canthaxanthin in certain amounts.

Tsubokura *et al.* teach to a process of mutating and culturing a strain such as E- 396, wherein the mutant strain Y-1071 is cultured for the production of canthaxanthin as claimed. See, e.g., Example 3.

The reference differs from the invention as claimed in that the amounts of canthaxanthin and other pigments products are not the same as claimed. However, the reference teaches methods of mutation suitable to obtain further mutants and in addition discloses that the manipulation of process conditions, such as concentration of dissolved oxygen affects the results obtained.

One of ordinary skill in the art would have had a reasonable expectation of success in using the process of Tsubokura *et al.* of mutation and selection and of manipulating oxygen content in the medium to obtain greater yields of canthaxanthin with the mutant obtained, for example.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Tsubokura *et al.* by subjecting the strains known to product canthaxanthin to further mutation and selection, if necessary, and/or manipulating process conditions to maximize the production of the valuable carotenoid canthaxantin.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at  $866_{6}217-9197$  (toll-free).

Irene Marx
Primary Examiner

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